# LETTERS TO THE EDITORS

**Regarding "Endovascular versus surgical treatment for thrombosed hemodialysis: a prospective, randomized study"**

*To the Editors:*

The recent article by Dougherty et al (J Vasc Surg 1999;30:1016-23) revisits several issues regarding thrombosed hemodialysis grafts. A flawed study design, insufficient information on the endovascular techniques used, and an incomplete cost analysis limit the applicability of the conclusions.

The study design lacks blinding. Despite randomization of the patients, there is potential for outcome bias when the same investigator performs both procedures. Deliverers of the therapies that are being directly compared for efficacy need to be blinded to the ongoing results of the study to ensure scientific integrity and prevent outcome bias.

The current endovascular technique for treatment of thrombosed hemodialysis grafts is mechanical catheter therapy. Urokinase is no longer commercially available because the Food and Drug Administration detected a number of problems regarding the processing and manufacturing of this drug.[1] Mechanical catheter therapy has been validated against both thrombolytic therapy and surgical therapy. In comparison with thrombolytic therapy, mechanical thrombectomy required less procedure time (75 minutes vs 89 minutes, $P < .04$) with equivalent 3-month patency as reported by Trerotola et al in 1998.[2] According to Uflacker et al in 1996,[3] mechanical therapy was similar in initial technical success, primary patency, and secondary patency to surgical thrombectomy.

Another point is the question of central venous stenosis as a cause for graft failure. Marston et al[4] recently reported central venous stenosis as a cause of graft failure in 15% of patients. In the interventional radiology suite, the central veins are routinely studied, and undergo fistulography. In this paper there is no mention of central venous evaluation. The cause of graft failure was not identified in seven (9%) of 80 patients. It is possible that central venous stenosis was missed causing graft rethrombosis. The information gathered by central venography is also useful in planning further graft placement.[4]

The authors fail to report the type of endovascular equipment used. How often was a second balloon needed? Furthermore, the average amount of urokinase used per patient is not reported. Urokinase is supplied in vials containing 250,000 units. How often was a second vial needed? Only rarely is more than one vial needed.

The cost analysis in this study as justification for use of surgical thrombectomy over endovascular therapy is problematic. Dougherty et al report longer procedure times and increased cost for endovascular therapy. However, Marston et al[4] reported equivalent costs between pulse-spray thrombolysis and surgical thrombectomy. Total procedure time is variable and dependent on the expertise of the physician, the complexity of the hemodialysis graft, and the venous lesion to be treated. Most endovascular therapy is performed in the radiology department, and therefore, a valid cost comparison compels the investigators to use radiology costs versus operating room costs. We speculate that the reported increased cost and time of the endovascular procedures may be operator dependent, institutional dependent, and device dependent. Furthermore, the large number of patients crossed over into the surgical thrombectomy arm from the endovascular arm may represent the technical bias of the investigators when faced with a complicated lesion.

The real issue is the optimization of patient care. This is best achieved with a complementary approach between the two therapies, each of which has its strengths and weaknesses. A combined multimodality approach is needed with refined algorithms to select the patients with the appropriate indications who will most benefit from the chosen therapy. Thus, multispecialty coordination among nephrologists, vascular surgeons, and interventional radiologists is needed to enhance patient care.[5]

*Michael C. Farner, MD*

Department of Radiology
Hospital of the University of Pennsylvania
Philadelphia, Pa

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**Reply**

Drs Farner and Sehgal raise several criticisms of our study. With regard to "blinding," this generally refers to the evaluator of outcome being blinded to the treatment group of a patient, which is impracticable (surgical patients obviously have incisions) and unnecessary (the primary end point of graft thrombosis is an objective

event). We disagree with the contention that having the same investigators perform both therapies biases results. Vascular surgeons in our institution perform the full range of endovascular interventions and have no intrinsic bias against endovascular techniques.

With regard to mechanical thrombectomy devices, Drs Farner and Sehgal state that these are "the current endovascular techniques." No doubt these devices are being widely utilized, but there certainly have been no prospective data validating this as the most efficacious approach, and at a cost of approximately $600 per catheter (substantially higher than urokinase cost) a cost advantage should certainly not be inferred. In the cited randomized study by Uflacker[1] published in the radiology literature, there is no life table patency analysis for this group of 37 patients. However primary patency at *30 days* was only 47% for mechanical thrombectomy patients, compared with 77% for surgical patients. In the study by Trerotola,[2] which was a prospective analysis of the author's proprietary device, over 60% of grafts had thrombosed within 90 days, results substantially worse than the endovascular arm of our trial or the trial by Marston.[3] With regard to the question of materials utilized in endovascular treatment, no artificial limits were set on the number of angioplasty balloons that could be used, though rarely were more than two catheters necessary. Only two patients had a second infusion of 250,000 units of urokinase, and the cost of urokinase and angioplasty balloons is reflected in the cost analysis. Central veins were evaluated routinely with digital fistulography in the operating room setting. Indeed, the two surgical crossovers were for balloon angioplasty of subclavian vein lesions. Though central vein stenosis may be a cause for inadequate dialysis and arm edema, it is rarely a cause for graft thrombosis, and the 9% rate of unexplained graft failure in our study is actually a lower proportion than described in most series.

We disagree that comparing radiology department costs with operating room costs is a more valid approach. The fact that operating room time is typically charged by the minute while angiography suite time is charged by procedure is an artifact of hospital accounting and billing techniques rather than a measurement of actual resource utilization. Indeed, surgeons could criticize the study in that most do not perform fistulography, which clearly added to the cost and time in the operative group; however, we felt for a bona fide comparison of techniques, keeping treatment protocols as similar as possible is preferred.

Although we concur with Drs Farner and Seghal that the cost and time of the procedure will vary between operators and institutions, it is a little foolish to simply acknowledge this and not attempt a prospective comparison for that reason. We disagree with the issue regarding surgical crossover, as we stated in our discussion. Reported rates of initial technical failure of 29% to 41% have been published in the radiology literature, and the alternative would have been to consider these patency failures. Indeed, when these procedures are performed in the radiology suite, increased costs are generated by the frequent need for these patients to have a second procedure in the operating room.

We do not disagree with the platitude that multiple specialty involvement can be beneficial. However, this does not obviate the need for prospective comparisons of newer technologies with accepted standards.

*Matthew J. Dougherty, MD*

Department of Vascular Surgery
Philadelphia, Pa

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## Regarding "Photoplethysmography and calf muscle pump function after subfascial endoscopic perforator ligation"

*To the Editors:*

I read with interest the article of Illig and collaborators from Rochester, NY, (J Vasc Surg 1999;30:1067-76) because of the need of assessment of functional results after a still controversial procedure in literature, the subfascial endoscopic perforator interruption (SEPS).

I agree that photoplethysmography (PPG) is an imperfect method with possible overlaps in evaluating venous function. On the other hand, venous function of the lower limbs has proved to be a difficult entity to quantify. Many other tests have been developed in an attempt to separate normal from abnormal function, including ambulatory venous pressure, foot volumetry, and air plethysmography. Unfortunately, none of the above methods can completely categorize patients and limbs by clinical severity of the disease. Despite this, PPG is an accepted tool for measuring surgical results.[1] Tracings like the one reproduced at the bottom of Fig 2 do not represent *uninterpretable results*; instead, they attest to an easily interpretable inability of emptying of the venous system after the procedure. This possibility has been well known since the time in which such a procedure was performed with an open technique.[2,3]

Elfstrom et al[2] demonstrate by the means of strain-gauge plethysmography that there was no increase in the expelled volume after the surgical procedure. This is confirmed by the comparison between clinical and PPG